F Series

Fresenius Medical Care

HF3000 and HF5000 Hemoconcentrators [REF. 9005391,9005371]

HF3000TSB and HF5000TSB Hemoconcentrators with Tubing Set and Collection Bag [REF. 9005381,9005361]

INSTRUCTIONS FOR USE

Indications for Use

The Fresenius F Series Hemoconcentrators are indicated to relieve or mitigate overhydration in patients undergoing cardiopulmonary procedures and to increase the concentration of cells and proteins in the blood.

Description

The Fresenius F Series Hemoconcentrators are high flux (permeability) ultrafiltration devices. Hemoconcentration is a technique used to separate plasma water from cellular blood components and plasma proteins. The procedure involves the selective removal of plasma water and its dissolved solutes by ultrafiltration. During therapy, plasma water and small and medium-sized solutes are removed in a controlled manner from extracorporeal blood while conserving the cellular blood components and proteins in the circulating blood.

The technique of ultrafiltration is applied to blood which is hemodiluted during cardiopulmonary procedures. When used in this application, the technique, known as Hemoconcentration, removes large quantities of plasma water in a relatively short time, thereby reconcentrating the red cell mass and plasma proteins.

Ultrafiltration occurs as a result of a hydrostatic pressure gradient across the semi-permeable membrane. The gradient is achieved by positive blood pressure supplied by a blood pump, and a negative filtrate pressure achieved either by siphon drainage or vacuum suction. The sum of the average positive pressure and the absolute value of the negative filtrate pressure is the hydrostatic transmembrane pressure. Transmembrane pressure is one regulator of the ultrafiltration rate. The rate of ultrafiltration also varies according to the hematocrit, protein content, and temperature of the blood, and the active surface area of the hemoconcentrator.

$$TMP = \frac{P_A + P_V}{2} + P_N$$

TMP = Transmembrane pressure (mmHg)
P_A = Arterial (inlet) pressure (mmHg)
P_V = Venous (outlet) pressure (mmHg)
P_N = Absolute value of any applied suction on the ultrafiltration outlet (mmHg)

The Fresenius F Series Hemoconcentrators are manufactured from glycerin-free Fresenius Polysulfone® membrane. The feature provides the convenience of insertion into the extracorporeal circuit at any time during a cardiopulmonary procedure without the need to rinse the hemoconcentrator. Each device is supplied in a sealed pouch to maintain a sterile, non-pyrogenic fluid pathway. When blood flows through the hemoconcentrator, it acts as an ultrafilter, removing a percentage of the plasma water and dissolved solutes from the blood. At the same time, the cellular blood components and proteins are retained in the concentrated blood, thereby producing a concentrated blood product. This product is intended for use by qualified personnel under the direction of a physician and by prescription only.

F Series Specifications	HF3000	HF5000
Overall unit length (cm)	29.5	29.5
Effective fiber length (cm)	23.0	23.0
Unit inner diameter (cm)	3.2	3.4
Active surface Area, nominal (m^2)	0.4	1.2
Fiber diameter (μm)	200	200
Fiber material	Polysulfone	Polysulfone
Pressure drop (nominal) $(mmHg)^2$	144	65
Max. Transmembrane Pressure (TMP) $(mmHg)^2$	600	600
Max. inlet blood flow rate (ml/min)	300	400
Priming Volume (ml)	30	72
Ultrafiltration Rate (ml/min)	See Figure 1 below	See Figure 2 below
Sterilizing Agent	Ethylene oxide	Ethylene oxide

1 End-to-end pressure drop; inlet conditions; Hct 25%, total protein 6.0 g/dl, Q_B 200 ml/min, temp. 37° C
2 Refer to TMP formula
3 Fresenius filtration performance studies; inlet conditions Hct 25%, total protein 6.0 g/dl, temp. 37° C. Refer to Figures 1 & 2 below. Filtration rate will vary according to blood flow rate (Q_B), TMP, temperature, hematocrit, and protein concentration.

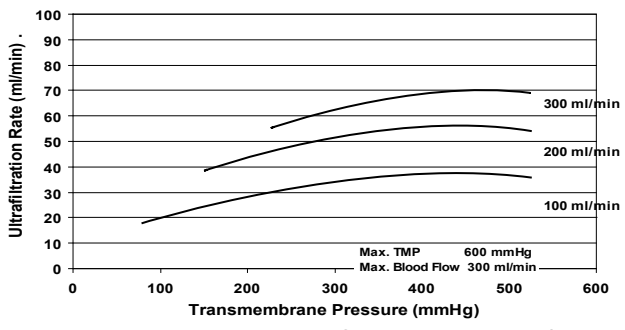

Figure 1: Fresenius HF3000 and HF3000TSB Hemoconcentrator ultrafiltration rates

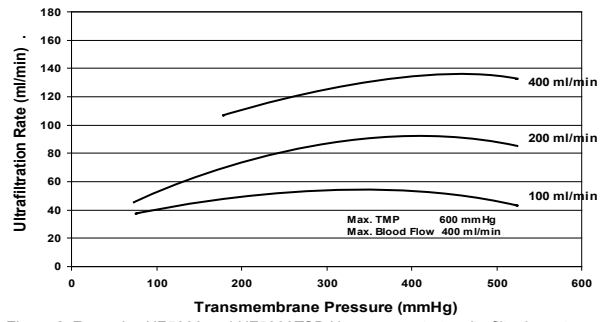

Figure 2: Fresenius HF5000 and HF5000TSB Hemoconcentrator ultrafiltration rates

Specifications: Fresenius HF3000TSB and HF5000TSB Hemoconcentrators with tubing set		
	Length: HF3000TSB / HF5000TSB	I.D. / O.D.
Arterial (inlet) line	24 in. (30 cm) / 36 in. (91 cm)	1/4 in.(6.5 mm) / 3/8 in.(9.5 mm)
Venous (outlet) line	24 in. (30 cm) / 36 in. (91 cm)	1/4 in.(6.5 mm) / 3/8 in.(9.5 mm)
Filtrate line adapter	Compatible with 1/4 in. I.D. x 3/8 in. O.D. tubing (6.5 x 9.5 mm)	
Inlet/outlet adapters	Male luer lock x 6.35 mm (1/4 in.) adapter	
Waste Collection	Filtrate Collection Bag with 36" drain line compatible with Filtrate line adaptor	

Specifications: Fresenius HF3000 and HF5000 Hemoconcentrators
For convenience, port adapters are assembled on the hemoconcentrator. Included are two twist lock connectors (Blood Inlet/Outlet) and one Hansen connector (Filtrate), both compatible with 6.35 mm (1/4 in.) tubing (not supplied).

Contraindications

While there are no known absolute contraindications to ultrafiltration therapy, extracorporeal blood circulation necessitates the administration of anticoagulants and other medications to the patient. All drugs and medications should be closely monitored by the prescribing physician to detect any alterations in the effective concentration due to the ultrafiltration process. Because the clearance of some drugs may be variable, the directions and contraindications for their use must be in keeping with the patient's medical history and status.

Warning and precautions

- Federal law (USA) restricts this device to sale by or on the order of a physician.
- This device is for single use only. **Do not reuse. Do not resterilize.**
- This product is sterilized with ethylene oxide (ETO). The blood pathway of this product is sterile and non-pyrogenic. Do not use if package is open or damaged or if the protective caps are not intact. Do not use if device is damaged. Connector covers should remain on device and bloodlines until time of connection.
- Read all instructions, cautions, and warnings before use.
- Use aseptic technique when making all connections.
- This device must be set up and used by personnel trained in the use of cardiopulmonary devices.
- Blood exiting the hemoconcentrator must always be directed to either a cardiotomy or venous reservoir. If any other return path is used, it should be evaluated for the potential to deliver air to the patient.
- Specific warning relating to the set up and use of this device or system are labeled in bold print. Warning and precautions should be thoroughly understood before operation of this device.
- All gaseous bubbles have the potential to embolize. The use of safety/warning devices for the detection and elimination of air in the extracorporeal circuit is recommended.
- Avoid storage temperatures below 5° C and above 30° C to assure optimal quality and performance.
- Do not exceed the recommended transmembrane pressure (TMP) and blood flow rate specified for this device.
- The ultrafiltrate should be continuously visually monitored for the appearance of blood, indicating a leak within the hemoconcentrator.
- The ultrafiltrate collector should be positioned below the level of the hemoconcentrator to prevent back filtration.
- This hemoconcentrator is made of a highly permeable membrane. Ultrafiltration will occur if the ultrafiltrate line is left unclamped, even in the absence of vacuum suction. If no ultrafiltration is desired, clamp the ultrafiltrate line.
- When this system is used in a cardiopulmonary bypass circuit, it must be connected to the positive output side of the blood pump.
- Blood flow must be from bottom to top of the device as indicated by the arrow on the device label.

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A. Set-up and use in cardiopulmonary circuits

Please refer to the following figures:

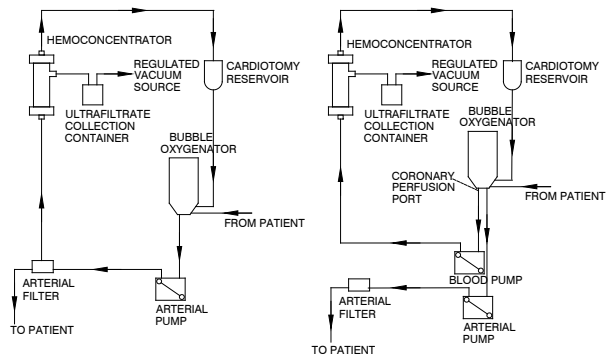

Figure 3: Suggested method(s) for using the Fresenius F Series Hemoconcentrators with a bubble oxygenator system.

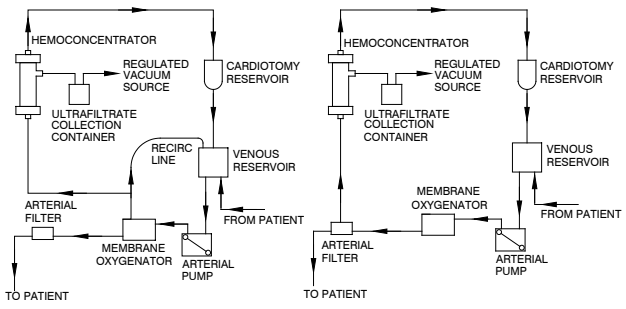

Figure 4: Suggested method(s) for using the Fresenius F Series Hemoconcentrators with a membrane oxygenator system.

CAUTION: Do not use if the package seal is broken or torn or if the end caps or port caps are missing. Do not use if bloodline connections (HF3000TSB, HF5000TSB) or blood port adapters (HF3000, HF5000) are detached from the hemoconcentrator.

CAUTION: Aseptic technique should be used when making all connections.

1. Remove the hemoconcentrator with attached tubing set from the shipping carton and inspect the sterile package for damage. Remove the device from the sterile pouch and confirm that the tubing and port caps are in place. Check that all connections to the hemoconcentrator are secure; tighten as necessary. Record the manufacturing lot number.

NOTE: The HF3000 and HF5000 do not include tubing. Assemble appropriate 6.35 mm (1/4 in.) tubing prior to use.

2. Mount the hemoconcentrator vertically to the pump mast. Make sure that the inlet port (line with the red end cap) is oriented downward. The direction of the blood flow through the device must be from bottom to top. Double check the orientation by confirming that the arrow on the hemoconcentrator label is pointing upward.
3. Connect the outlet blood tubing either to the cardiotomy or venous reservoir. If a male luer lock fitting is required to make this connection, ensure a secure connection by pushing the blood tubing all the way to the male luer lock collar.
4. Connect the inlet blood tubing in the extracorporeal circuit that will provide blood flow not exceeding 300 ml/min (HF3000 and HF3000TSB) or 400 ml/min (HF5000 and HF5000TSB). (Refer to Figures 3 and 4). If a male luer lock fitting is required, attach it in the same manner recommended above.
5. Attach ¼ inch I.D. tubing to the Hansen adapter on the ultrafiltrate port. Connect the other end of the tubing to a graduated collection container. HF3000TSB and HF5000TSB include a Filtrate Collection Bag with attached drain line for connection to the Hansen adapter. Vacuum pressure is not required with the Fresenius F Series hemoconcentrators; however, if siphoning action is to be used to supply negative pressure, place the open container below the level of the hemoconcentrator to facilitate siphoning and prevent back filtration. To produce a higher ultrafiltration rate, a vacuum suction can be attached to the top of a closed vacuum collection container to create higher negative pressure. Clamp the ultrafiltrate tubing.
6. If it is anticipated that the hemoconcentrator will be used during CPB, the system can be primed initially along with the rest of the circuit. To prime the hemoconcentrator, allow priming solution to flow through the inlet port and out the outlet tubing while the ultrafiltrate tubing is clamped. Gently tap the outlet port end cap to remove any air in the hemoconcentrator.
7. When all of the air has been removed, unclamp the ultrafiltrate line and clamp the outlet tubing. If a roller clamp is being used on the outlet line, do not totally occlude the outlet blood tubing to avoid exceeding the recommended TMP of 600 mmHg.

Clamping the outlet blood tubing will force priming solution across the filter membrane, filling the ultrafiltrate compartment and the ultrafiltrate tubing. If a roller pump is being used on the inlet blood line, close it as soon as the ultrafiltrate tubing is full. Clamp the inlet, outlet, and ultrafiltrate tubing. The hemoconcentrator is primed and ready to use.

WARNING: Do not exceed a TMP of 600 mmHg. If vacuum suction is being used for additional fluid removal, it is recommended that a vacuum regulator be used to assure that the maximum recommended TMP of 600 mmHg is not exceeded at any time. When using vacuum suction on the ultrafiltrate line, increase and decrease the vacuum settings gradually. Membrane leakage may occur if the vacuum setting is changed rapidly. If a dedicated pump is used for blood supply, it is recommended that the generated inlet pressure be closely monitored and controlled to assure the maximum TMP of 600 mmHg is not exceeded at any time. Refer to formula on front page for determination of TMP.

B. Operation during cardiopulmonary procedures

1. To establish blood flow through the hemoconcentrator, unclamp the blood outlet tubing and then the blood inlet tubing. Leave the ultrafiltrate tubing clamped. Circulate blood through the device for approximately three (3) minutes to displace the priming solution and any residual air. During this period, the device and all connections should be examined for leaks or malfunctions. Tighten or replace, if necessary.
2. To begin ultrafiltration, remove the clamp on the ultrafiltrate tubing. Filtrate will flow into the collection container at a rate easily controlled by the blood flow rate and hydrostatic pressure gradient. The hydrostatic pressure gradient is affected by the height differential between the hemoconcentrator and the collection container, and/or by the amount of vacuum suction applied.

NOTE: Factors in addition to the hydrostatic pressure gradient and the blood flow rate affecting the ultrafiltration rate are protein concentration, hematocrit, and temperature.

WARNING: The hemoconcentrator will ultrafilter blood when the ultrafiltrate line is open. If no ultrafiltration is desired, clamp the ultrafiltrate line.

3. Once blood has been introduced into the hemoconcentrator, it is recommended that uninterrupted blood flow through the device at no less than 100 ml/min to prevent clotting.

WARNING: The ultrafiltrate line should be clamped to prevent ultrafiltration if blood flow through the device is stopped.

4. The filtration rate is easily determined by reading the volume per unit time of collected filtrate, or by measuring the weight collected per unit time. **Note: Air entrapped in the Filtrate Collection Bag may interfere with accuracy of indicated filtrate volume. Measurement accuracy may be improved after procedure by disconnecting drain line from Hemoconcentrator and allowing air to vent from bag before reading volume collected. For best volumetric measurement, contents may be weighed.**

C. Installation of hemoconcentrator into circuit during a procedure

1. If the hemoconcentrator is to be integrated into a circuit after a cardiopulmonary procedure has begun, simply install the hemoconcentrator into the appropriate place in the circuit. Clamp only the ultrafiltrate line. Establish blood flow through the device and gently tap the outlet end cap to displace air into the cardiotomy or venous reservoir.

NOTE: A slight pinkish color may be noted in the ultrafiltrate during the first 1-2 minutes of filtration if an unprimed filter is being used. If this effect does not resolve during the first few minutes of initial use, replace and prepare the filter as previously described.

WARNING: Do not connect the blood outlet tubing line at any location in the circuit where air bubbles could enter the patient directly.

2. After blood has circulated through the hemoconcentrator for several minutes and all air has been removed, unclamp the ultrafiltrate line to begin ultrafiltration.

NOTE: Vacuum suction may be necessary to start the flow of ultrafiltrate. Allow 3-4 minutes for the ultrafiltrate compartment to fill with fluid. Once ultrafiltrate flow has been established, suction can be discontinued, if desired.

3. The hemoconcentrator can now be operated as described previously.

D. Monitoring

1. A minimum blood flow rate of 100 ml/min should be maintained throughout the procedure to prevent stagnation and potential clotting.
2. Blood flow must not exceed 300 ml/min (HF3000) or 400 ml/min (HF5000) and transmembrane pressure must not exceed 600 mmHg.
3. During use, if red blood cells appear in the ultrafiltrate, a fiber rupture has occurred. The device should be replaced and prepared as previously described.

WARNING: Ensure proper fluid balance. Improper fluid balance can result in a condition of either hypervolemia or hypovolemia, presenting potentially serious hazards to the patient.

E. Post procedure hemoconcentration

1. Blood remaining in the circuit after the cardiopulmonary procedure may be concentrated by continuing the ultrafiltration process, and then returning the concentrated blood to a transfer pack for intravenous infusion to the same patient.

WARNING: Because of the high permeability of this hemoconcentrator, a high concentration of red cell mass is easily attained. Concentration beyond a hematocrit of 50% is not recommended.

WARNING: When returning heparinized concentrated blood to the patient, it may be necessary to administer additional protamine.

Discard the extracorporeal circuit in an appropriate biohazard waste receptacle. Reference: 29CFR 1910.145, 1910.1030 (Code of Federal Regulations) and appropriate state of local codes.

Fresenius Medical Care
FRESENIUS MEDICAL CARE NORTH AMERICA
WALTHAM, MA 02451
1-800-323-5188
Made in the USA

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